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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Examiner: Duffy, P.

Heath *et al.* Group Art Unit: 1645

Serial No.: 08/699,716 Atty Docket: 003/029/SAP

Filed: August 27, 1996

For: Recombinant F1-V Plague Vaccine

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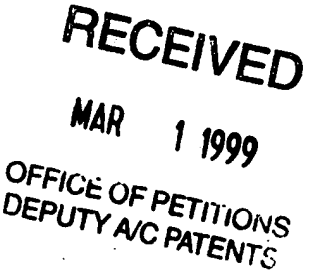
February 22, 1999

SUPPLEMENTAL RESPONSE



Honorable Commissioner of
Patents and Trademarks
Washington, D. C. 20231

Sir:

This is in response to the Office Action dated June 19, 1998 in the subject application. Applicants appologize for the omission in the Response dated April 10, 1998.

Reconsideration and allowance in view of the following additional remarks are respectfully requested.

Claims 1-10, 12-17 and 30 stand rejected under 35 U.S.C. §112, first paragraph as allegedly nonenabling for DNA encoding mutants, or truncations or SEQ ID NO:1 or 2. The claims as amended are drawn to the entire sequence or F1 or V of *Yersinia pestis*, and the objectional language "a portion thereof" has been removed. Natural or synthetic variants claimed are expected to encode F1 and V antigens.

It would not require undue experimentation by a person with ordinary skill in the art to produce synthetic variants, which differ in nucleotide sequence but still encode the desired antigen, for example, due to codon redundancy. In addition, protective epitopes of these proteins are known in the art (please see page 9, line 10-11 where the reference by Motin *et al.*, 1994 is cited). In light of the present disclosure, it would not require undue experimentation for a person with ordinary skill in the art to realize which of the nucleotides could be altered without affecting the immunological effect of the resulting F1-V peptide. In fact, when Applicants sequenced F1-V fusion DNA fragment of the present invention, two nucleotides were different between the F1-V fusion fragment and the previously published V antigen, as disclosed on page 16, lines 14-19. One of the differences resulted in no change in the amino acid at that site, and the other one resulted in a change from alanine to threonine indicating that these differences occur without affecting the ability of the DNA to encode F1-V fusion protein.

Due to the high skill of people in the art of molecular biology and due to a clear description of the required characteristics of the final DNA fragment claimed, in addition to the degree of knowledge of F1 and V sequences, adequate guidance with regard to producing an F1-V fusion protein, or a variant as claimed is provided and undue experimentation would not be required to practice the

invention. Reconsideration and withdrawal of the rejection are respectfully requested.

All objections and rejections have been addressed. This application is believed to be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,

By _____ Reg. No. 39,441
for Charles H. Harris
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I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the

Commissioner of Patents
Washington, D.C. 20231

on February 22, 1999.

By _____
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